

**REMARKS**

Claims 26 and 33-50 are currently pending. Support for claim amendments and new claims is found in the Specification as filed as follows:

Claim	Support	
26, 35	cancer cell	Page 3, lines 15-17 Page 4, lines 24-28 Page 31, lines 18-23 Page 35 line 32-page 36, line 4 Page 37, lines 20-24 Pages 55-56 (Example 7)
	SEQ ID NO: 4	Page 12, lines 19-25
	SEQ ID NO: 6	Page 9, Table 1, row 6
	95% identity	Page 16, line 6; Page 15, lines 19-21.
49	Page 32, lines 7-14 and lines 26-30 Page 12, lines 9-15 Page 22, lines 23-29	
50	Pages 55-56 (Example 7)	

No new matter has been added herewith. The following addresses the substance of the Office Action.

**Oath/Declaration**

Non-initialed and non-dated alterations were made to the oath or declaration on page 3. Submitted herewith is a copy of the Declaration wherein the alterations are initialed and dated.

**Rejection under 35 112, First Paragraph (Written Description)**

Claims 26, 33-34 and 36 were rejected as failing to comply with the written description requirement. In particular, the Examiner stated that the applicants are not in possession of a gene encoding a StarD10 polypeptide, which encompasses promoter nucleotide sequences and intron and exon nucleotide sequences, but are only in possession of the cDNA that encodes the said polypeptide. However, Claim 26 and dependent claims thereof were not directed to a method comprising screening the level of a gene encoding a StarD10 polypeptide. Instead, they were directed to a method that comprises screening the level of an expression product of a gene encoding a StarD10 polypeptide. Claim 26 and dependent claims thereof are amended here to

further specify that the expression product is from a polynucleotide having a sequence selected from the group consisting of SEQ ID NO: 4, a polynucleotide that encodes SEQ ID NO: 6 and a polynucleotide sequence having 95% identity to either of the foregoing. Supporting language in the Specification is summarized above.

As elaborated in claim 33 and withdrawn claim 35, expression products include polypeptide and RNA embodiments. Referring to the Specification as filed on Page 22, an aspect of the invention contemplates an expression product of StarD10. The expression product may be a polypeptide encoded by the open reading frame of StarD10 (i.e. see SEQ ID NO: 5 or SEQ ID NO: 6) or it may be an mRNA, an RNA molecule spliced from an mRNA, or precursor a form thereof. Such RNA molecules may include exons and introns.

In view of the preceding remarks, Claims 26, 33-34 and 36 are in compliance with 35 U.S.C. § 112, first paragraph, with respect to written description and the Applicants respectfully request removal of the rejection.

**Rejection under 35 U.S.C. § 112, First Paragraph (Enablement)**

Claims 26, 33-34 and 36 were rejected as not being enabled by the Specification. The Examiner stated that, while being enabling for a method for detecting the presence of a cancerous breast epithelial cell in a subject or in a biological sample, the Specification does not reasonably provide enablement for a method for detecting the presence of an aberrant cell in a subject or a biological sample. The Applicants have amended Claim 26 and dependent claims thereon by replacing the term aberrant cell with “cancer cell”. Support for the claimed methods for detecting the presence of a cancer cell is found throughout the Specification as summarized above. In particular, referring to Example 7 on pages 55-56, an elevated level of StarD10 (i.e., an expression product of a polynucleotide having a sequence selected from the group consisting of SEQ ID NO: 4, a polynucleotide that encodes SEQ ID NO: 6 and a polynucleotide sequence having 95% identity to either of the foregoing) is associated with both breast cancer and colon cancer. In particular, overexpression of StarD10 was found in multiple cell lines derived from these cancers. Based on the identification of all of these unrelated cancer cell lines as overexpressing StarD10, one skilled in the art would reasonably expect StarD10 overexpression to be indicative of other cancers. The Applicants respectfully request removal of the rejection under 35 U.S.C. § 112, first paragraph regarding enablement.

**Application No.: 10/538,704**  
**Filing Date: February 21, 2006**

**Rejection under 35 U.S.C. § 112, Second Paragraph (Indefiniteness)**

Claims 26, 33-34 and 36 were rejected as being indefinite. In particular, the Examiner stated that the term “StarD10” was indefinite and suggested that the claims be amended to specify a SEQ ID No identifier that clarified the meaning of StarD10. As suggested by the Examiner, Claim 26 is amended to specify disclosed or known sequences (i.e., a method comprising screening the level of an expression product of a polynucleotide having a sequence selected from the group consisting of SEQ ID NO: 4, a polynucleotide that encodes SEQ ID NO: 6 and a polynucleotide sequence having 95% identity to either of the foregoing.) In view of the amendment, the claims are believed to be definite and removal of the rejection is earnestly solicited.

**No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

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### CONCLUSION

In view of Applicants' amendments to the Claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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